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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,409	04/13/2000	Lance E. Steward	17282CIP(AP)	7255

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EXAMINER	
NOLAN, PATRICK J	
ART UNIT	**PAPER NUMBER**
1644	16

DATE MAILED: 08/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/548,409	Stewart et al.
Examiner	**Art Unit**
Patrick J. Nolan	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 14, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above, claim(s) *14-19* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-13* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *2 and 3*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Part III DETAILED ACTION

1. Claims 1-19 are pending.

2. Applicant's election of Group I, claims 1-13 in Paper No.6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 14-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

3. Applicant is notified that they have not complied with 37 CFR 1.821-1.825 because they have not inserted SEQ ID NOS. for the peptides disclosed on page 26 lines 8-9.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a fusion protein comprising a first element that specifically binds to pancreatic acinar cells, wherein said element is selected from the group consisting of SEQ ID Nos 2-6,;a second element that facilitates translocation of the polypeptide selected from the N-terminal peptide half of either the heavy chain of C tetanus neurotoxin or C botulinum neurotoxin; a third element that is a therapeutic element that inhibits enzymatic secretion by an acinar cell of the pancreas selected from BoNT/A-G or TeNT ; does not reasonably provide enablement for any binding element able to specifically bind any pancreatic cell surface marker or any second element that facilitates translocation of a polypeptide and any therapeutic element that inhibits enzymatic secretion of pancreatic acinar cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

Applicant's claimed invention is drawn to a composition for treating acute pancreatitis. However, by creating a fusion protein that specifically binds any pancreatic cell surface marker the scope of Applicant's claimed invention would include targeting

cells in the pancreas that are not involved in acute pancreatitis, such as ductal cells, the alpha, beta and delta cells of the islets of Langerhans. For Applicant's claimed invention to predictably work, Applicant's claims would necessarily be limited in scope to targeting acinar cells, which Applicant's own specification are responsible for causing acute pancreatitis. Furthermore, since Applicant's prophetic specification is limited in the recitation of which binding agents can bind the acinar cells specifically, SEQ ID NOS 2-6, translocation elements comprising the N-terminal peptide half of either the heavy chain of C tetanus neurotoxin or C botulinum neurotoxin and a third element that is a therapeutic element that inhibits enzymatic secretion by an acinar cell of the pancreas selected from BoNT/A-G or TeNT and there is no more specific guidance besides these compounds in practicing the invention, it would be unpredictable and require an undue amount of experimentation to practice the full scope of Applicant's claimed invention drawn to any binding agent.

5. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is insufficient written description to show that Applicant was in possession of any "binding element" which will be able to bind specifically to a CCK-A or CCK-B receptor other than SEQ ID NOS 2-6; any second element that facilitates translocation of the polypeptide other than the N-terminal peptide half of either the heavy chain of C tetanus neurotoxin or C botulinum neurotoxin; and any third element that is a therapeutic element that inhibits enzymatic secretion by an acinar cell of the pancreas other than BoNT/A-G or TeNT . The term binding element, translocation element of therapeutic element would include an essentially unlimited number of undefined compounds. One of skill in the art would therefore conclude that the specification fails to disclose a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

Applicant is directed to the Written description guidelines from the Federal Register Vol. 66, No. 4, Friday January 5, 2001

For each claim drawn to a genus:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, *i.e.*,

structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A ''representative number of species'' means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. On the other hand, there may be situations where one species adequately supports a genus. What constitutes a ''representative number'' is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a ''representative number''depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 USC 112 1st paragraph.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

7. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
August 8, 2002